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|----------------------|-------------|----------------------|----------------------|------------------|
| APPLICATION NO.      | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.  | CONFIRMATION NO. |
| 10/585,017           | 08/04/2008  | Jacob Bar-Tana       | 15677/76581/JPW/CH   | 7859             |
| 23432                | 7590        | 04/19/2011           | EXAMINER             |                  |
| COOPER & DUNHAM, LLP |             |                      | SZNAIDMAN, MARCOS L. |                  |
| 30 Rockefeller Plaza |             |                      | ART UNIT             | PAPER NUMBER     |
| 20th Floor           |             |                      |                      | 1628             |
| NEW YORK, NY 10112   |             |                      | MAIL DATE            | DELIVERY MODE    |
|                      |             |                      | 04/19/2011           | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|                              |  |  |
|------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/585,017   | <b>Applicant(s)</b><br>BAR-TANA ET AL. |
|                              | <b>Examiner</b><br>MARCOS L. SZNAIDMAN | <b>Art Unit</b><br>1628                |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 06 April 2011.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 2-19 and 22-31 is/are pending in the application.
  - 4a) Of the above claim(s) 2-10 and 12-19 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 11 and 22-31 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-878)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No./Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
 Paper No./Mail Date \_\_\_\_\_
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_

### **DETAILED ACTION**

This office action is in response to applicant's reply filed on April 6, 2011.

The finality of the previous office action mailed on February 10, 2011 is being withdrawn, and is being replaced with this NON-FINAL office action.

#### ***Status of Claims***

Claims 2-19 and 22-31 are currently pending and are the subject of this office action.

Claims 2-10 and 12-19 were withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claims. Election was made **without** traverse in the reply filed on April 26, 2010.

Claims 11 and 22-31 are presently under examination.

The following species is under examination: Dyslipoproteinemia as the disease being treated.

#### ***Priority***

The present application is a 371 of PCT/IL04/001185 filed on 12/30/2004, and claims priority to provisional application No. 60/533,639 filed on 12/30/2003.

#### ***Rejections and/or Objections and Response to Arguments***

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated (Maintained Rejections and/or Objections) or newly applied (New Rejections and/or Objections, Necessitated by Amendment or New Rejections and/or Objections not Necessitated by Amendment). They constitute the complete set presently being applied to the instant application.

***Claim Rejections - 35 USC § 103 (New Rejection)***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11 and 22-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bar-Tana (US 4,689,344).

For claims 11 and 22-24 and 30-31 Bar-Tana 1 teaches a method of treating hypercholesterolemia and hypertriglyceridemia (dyslipoproteinemia is a combined hypercholesterolemia and hypertriglyceridemia, see specification page , lines 14-15) in Psamomys Obesus (see column 20, line 65 through column 22, line 24, and more specifically table VI) comprising the administration of 3,3,14,14 tetramethyl hexadecane 1,16 dioic acid ( MEDICA 16 or M16, see column 8, example 4). The animals were fed with "Amrod 935" Purina Chow diet supplemented with 0.1% of the active compound (see column 20, lines 65 through column 21, line 3). Bar-Tana further teaches that the daily dosage will depend on the age, needs and tolerance of the

individual patient, but it will usually range from 50 mg to 5,000 mg per day (see column 7, lines 7-14).

Bar-Tana does not teach the dose ranges from about 30 mg per day to about 400 mg per day as disclosed in claim 11 or the dose range recited in claims 22-24 and 30-31. However, the dosage taught by Bar-Tana (50 to 5,000 mg daily, see above) clearly overlaps with the dosages of the instant claims (30 to 400 mg daily, 100 to 400 mg daily, 200 to 400 mg daily, 100 to 200 mg daily, and 200 mg). MPEP 2144.05 states: In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). Thus resulting in the practice of claims 11, 22-24 and 30-31 with a reasonable expectation of success.

For claims 25-29, Bar-Tana further teaches that the daily dosage of the compound of formula (I) will depend on the age, needs and tolerance of the individual patient (see column 7, lines 7-14).

At the time of the invention, it would have been *prima facie* obvious for a person of ordinary skill in the art to further optimize the dose regimen based on age, tolerance and the individual needs of the patient as taught by Bar-Tana, thus resulting in the practice of claims 25-29 with a reasonable expectation of success.

***Withdrawn Rejections and/or Objections***

***Claims rejected under 35 USC 103 (a)***

Applicant's arguments have been fully considered and are persuasive.

Rejection under 35 USC 103(a) is withdrawn.

However, upon further consideration and based on new prior art, a new 103(a) rejection, not necessitated by amendment has been applied (see above).

***Conclusion***

No claims are allowed.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCOS SZNAIDMAN whose telephone number is (571)270-3498. The examiner can normally be reached on Monday through Thursday 8 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on 571 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MARCOS L SZNAIDMAN/  
Primary Examiner, Art Unit 1628  
April 18, 2011.